

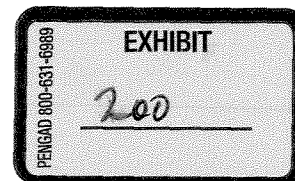
# EXHIBIT 57

**REPORT TO CONGRESS**

**THE AVERAGE WHOLESAL PRICE  
FOR DRUGS COVERED UNDER MEDICARE**

**DONNA E. SHALALA  
SECRETARY  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
1999**

**HHC902-0801**



## I. INTRODUCTION

### PURPOSE.—

Sections 4556(a) and (b) of the Balanced Budget Act of 1997 (BBA) amended section 1842 of the Social Security Act to provide, effective January 1, 1998, a new method for establishing the payment limit for drugs and biologicals covered under the Medicare program and not paid on a cost or prospective payment basis. That payment limit is equal to 95 percent of the average wholesale price (AWP) of the drug. Section 4556(a) of the BBA requires the Secretary, by July 1, 1999, to report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate, the effect, if any, that the new payment limit may have had on the AWP of these drugs and biologicals. The following is that report.

### HISTORY.—

Medicare has a limited prescription drug benefit outside the hospital inpatient setting. The basic benefit covers only drugs that are furnished incident to a physician's service and that cannot be self-administered. There are very few statutory exceptions to this general exclusion of drugs that can be self-administered. Some examples include immunosuppressive drugs, hemophilia clotting factors, erythropoietin for trained home dialysis patients, allergens under certain conditions, and certain oral anti-cancer drugs. Also covered are a very few drugs that are used in conjunction with Medicare covered durable medical equipment; e.g., inhalation drugs used with a nebulizer.

Traditionally, Medicare has paid for drugs and biologicals (hereinafter referred to as "drugs") under several payment methodologies. Drugs are paid on a cost basis when furnished to hospital outpatients. Drugs are paid on a prospective payment basis when furnished to hospital inpatients under the hospital prospective payment system and when furnished to end stage renal disease (ESRD) patients paid under the ESRD composite rate. Drugs not paid on a cost or prospective payment basis were paid based on the lower of the billed charge or the AWP as reflected in commercial sources such as Red Book, Blue Book, or Medispan. If the drug was a multi-source product, then the program payment limit would be equal to the lowest AWP of all the generic forms of the product. In 1991, we published a final rule to revise the regulations to set payment at the lower of the estimated acquisition cost (EAC) or the AWP. For multi-source products, the limit was equal to the lower of the EAC or median AWP of all generic forms of the product. These regulations were never implemented due to paperwork and reporting burdens and problems associated with statistical sampling that would be used to determine the EAC.

For the past 13 years, the Office of Inspector General (OIG) has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than the AWP. To address this problem, the President's 1997 budget contained a

legislative proposal that would have based payment on the lower of the billed charge or the actual acquisition cost (AAC) for the drug of the physician or supplier billing Medicare. However, as discussed above, in the BBA, Congress rejected this proposal in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of AWP. The Medicare Part B coinsurance and deductible requirements apply to this benefit.

#### BACKGROUND.—

The AWP is not a well-defined concept nor is it regulated in any way. OIG reports that the AWP is set by the manufacturer as a suggested price and published in various commercial sources. However, it is not truly an average of wholesale prices because very few purchasers actually pay this amount.

Rather, the AWP is used as a standard benchmark, with negotiated prices often expressed in terms of AWP minus a certain percentage. OIG found that the AWP published in the commercial sources for 22 of the top drugs paid by Medicare is not representative of any price that is actually charged by wholesalers to their customers. The OIG's most recent studies are "Excessive Medicare Payments for Prescription Drugs" (OEI-03-97-00290, December 1997), and "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" (OEI-03-97-293, November 1998). On average, for the 22 drugs in the OIG study, Medicare payment at the AWP allowed a markup of 41 percent above the drugs' wholesale catalog price advertised to the physicians and suppliers who bill Medicare.

#### II: Data

In order to analyze any changes in the AWP due to enactment of section 4556 of the BBA, we first identified all Medicare Part B charges involving pharmaceutical claims using the HCFA Common Procedure Coding System (HCPCS). Relevant codes in the HCPCS were then ranked by total Medicare allowed charges processed by Medicare carriers in 1997. The rank distribution indicates that total allowed charges for the top 50 drug-related codes accounted for 93.48 percent of the total allowed charges for all Medicare claims for drugs processed by carriers. Table 1 lists the top 50 drugs, their allowed charges for 1997 and the percent those charges represent of total Medicare charges for drugs. Because the remaining drug codes account for an insignificant amount of benefit payments, we have focused our analysis on the top 50 codes.

We subsequently excluded 6 codes from the top 50 list. In general, these codes were excluded because they represent more than one drug product and, thus, cannot be evaluated in terms of a specific AWP. Influenza immunization (code, 90724) represents a

number of different vaccines that are based on different viruses. Other codes could not be mapped to particular drugs as they are broad categories of drugs, such as, J9999, other chemotherapy drugs, or J3490, unclassified injections. Therefore, the remainder of our analysis is based on the remaining 44 drugs.

We obtained our data on AWP from the January 13 electronic version of First Data Bank drug pricing data. Commonly referred to as the Blue Book, this data file lists the most current, as well as historical, AWP's and dates of revisions to the AWP for all pharmaceutical products identified by an 11-digit National Drug Code (NDC). In this analysis, we considered each 11-digit NDC as a drug product as it uniquely describes the drug by manufacturer, drug compound, and unit dosage package. In order to present a long-term perspective, we obtained AWP data spanning a total of 7 years beginning January 1, 1992 through December 31, 1998. Contained in our Medicare part B drug-related HCPCS are 795 separate drug products (NDCs). The comparison group for the study is composed of the entire group of prescription drugs approved by the Food and Drug Administration (FDA). The comparison group numbered 48,922 drug products as represented by individual NDCs.

### III. Method

In order to examine changes in prices, we developed price indices from the AWP data. To preserve consistency of the price indices over time, we excluded all obsolete drugs from the analysis data base. We defined obsolete drugs as those drugs that existed at sometime during the analysis period, but, as of December 1998 are no longer manufactured. Although a few products are pulled from the market for adverse clinical outcomes, other causes for obsolescence include changing manufacturing entities and revisions in unit dosage packaging. Thus, a majority of obsolete drugs are replaced by other drugs that are incorporated in this analysis. This process resulted in the inclusion of 795 Medicare covered drugs and approximately 49,000 prescription drugs by NDC.

Drugs were classified in the Medicare covered group and the comparison group by patent and marketing exclusivity status. As shown in Table 2, this resulted in three classes of drugs in each group: brand single source, brand multi-source, and the generics. For each of the six classes of drugs, we constructed a simple average price index using the first quarter 1992 price as the base period.<sup>1</sup> This simple average of the AWP is an inferior

---

<sup>1</sup>Many widely used price indices, such as the Consumer Price Index (CPI) and the Producer Price Index (PPI), are quantity-weighted average prices calculated from a sample of commodities. Although weighted price indices have additional desirable properties, constructing weighted price indices from the Medicare claims data system is not possible because the claims billing codes are generally not specific to dosage levels or manufacturers. Consequently, we adopted an unweighted average price indexing method.

measure of economy-wide drug price levels because the AWP only suggests a baseline price in the trade. However, this indexing method is entirely appropriate for Medicare because its payment rule uses the median AWP in calculating its payment limit. A detailed description of the price indexing method is provided in the appendix.

#### IV. The Analysis

##### A. The Long Run AWP Trend for Medicare Drugs

First, we present the average Medicare drug AWP index along with the consumer price index for prescription drugs (CPI-Rx) in Figure 1. The CPI-Rx is a weighted average price of pharmaceuticals and other medical supplies calculated by the Department of Labor, Bureau of Labor Statistics. As a weighted average price of a subset of pharmaceuticals for urban consumers, it represents different elements of drug pricing. With this caveat, the CPI-Rx is presented for comparison purposes. The price indices are calculated using prices at the end of each year.<sup>2</sup>

As demonstrated in Figure 1, the Medicare drug inflation rate closely tracks the CPI-Rx inflation rate, indicating a high degree of parallelism (with a correlation coefficient of 0.982). However, while the Medicare AWP index trailed the CPI-Rx through the first half of 1998, it then rose above the CPI-Rx index in the second half of 1998.

A comparison of Medicare AWP and industry-wide AWP is presented for each drug class in Table 3. The annual average growth rate of the AWP for Medicare covered drugs is lower than the industry-wide average AWP growth rate. Over the entire period between January 1992 through December 1998, Medicare brand single source drugs had an inflation of 19.84 percent with an annual average of 2.64 percent. This is 8.27 percent less than the industry-wide average for the brand single source drugs. On the other hand, the Medicare covered brand multi-source drugs showed a much higher inflation rate of 32.23 percent, corresponding to an average annual rate of 4.08 percent. It is noteworthy that this rate of inflation is the highest among the three classes, closely tracking the industry-wide average of 32.31 percent. Contrary to a conventional perception that the generic drug prices are closely checked by the competitive forces in the market, the generic price index growth was 24.94 percent (3.26 percent annually) for Medicare drugs

HHC902-0805

<sup>2</sup>The observations for 1991 are exceptions. They were based on January 1, 1992 prices.

during the 7 year period. Moreover, the data show that the industry-wide average inflation rate was the highest for this group at 48.08 percent during this period.

Averaging annual growth rates over time has a potential inaccuracy. Two data series may have the same average inflation rate over the same period, but one may reach a higher level than the other. When one series has relatively higher growth rates in the earlier period than the other, it can reach a higher level at the end due to the power of compounding.

In order to visually present the inflation rates without this potential bias, we calculated each price index as a difference from the market AWP average for each class. The results are graphically shown in Figure 2. In this diagram, any points above the 0 percent line indicate that the index exceeded the industry-wide AWP growth rate; and any points in the negative indicate the index lagged the industry-wide average. Once corrected for this bias, it is evident from Figure 2 that the average AWP for brand multi-source drugs stayed above the market average between 1993 and 1997. It was not until 1998 that this index declined to the industry-wide average level. Conversely, our estimate for the brand single source and generic drugs consistently lags below the industry-wide AWP level. In particular, the gap between the industry-wide AWP average and the Medicare generic drug index has been widening since the beginning of our observation period (1992). The difference reached approximately 23 percent by 1998.

In Figure 3, Medicare AWP's are compared to CPI-Rx for the same period. The comparison shows that the generic price index grew at a higher rate than the CPI-Rx. In addition, by 1998, brand multi-source drug prices exceeded the CPI-Rx. Conversely, the brand single source drug index was lower than the CPI-Rx for the entire data period. It is important to note that drug expenditure growth in recent years is driven to a significant extent by the introduction of expensive brand drugs. Since our pricing method fails to capture such a trend, our index for brand drugs contains a certain downward bias.

#### B. Medicare AWP Growth Before and After BBA

An important objective of this report is to determine if there was a difference in the growth of Medicare covered drug prices in the period following the enactment of the BBA drug payment provision. To assess the impact, a benchmark date is needed that divides the AWP's for Medicare covered drugs into two periods. One possible benchmark is the implementation date for the BBA payment provision (January 1, 1998). An alternative possibility is the date of the first legislative proposal suggesting a payment provision, under the assumption that anticipation of the payment reform would begin to influence the industry's pricing strategy immediately. This second date is January 1997.



In this report, we considered both of these benchmarks to analyze the effects of the BBA payment provision on the AWP.

Using the method described above, we calculated the average rate of inflation for each group.<sup>3</sup> First, using January 1997 as a benchmark, we compared the average rates of inflation between the two periods i.e., before January 1997 and after January 1997 we will refer to this period as the "post-BBA" period. Figure 4 shows that there was an elevated rate of inflation for all classes of drugs in the post-BBA period. All three classes of Medicare covered drugs recorded a higher rate of price increase in this period. While this trend is consistent with the overall trend in the AWP, it is important to note that the CPI-Rx inflation rate actually declined by 20.65 percent in the post-BBA period.

The greatest average growth rate is in the generic drug class, where AWP inflation was 5.04 percent per year, compared to only 2.55 percent per year growth pre-BBA. This is equivalent to a 97 percent increase in AWP inflation rate in the post-BBA period. The post-BBA rate substantially exceeds the CPI-Rx growth of 3.18 percent. In the brand multi-source drug class, we observed a sizeable increase in AWP inflation rate. Compared to the pre-BBA period, the AWP index for this class of drugs increased 25.6 percent. The brand single source drug class showed the lowest increase in AWP inflation rate in the post-BBA period at 8.82 percent, as well as the lowest inflation levels overall.

Alternatively, we examined the data using the implementation date as the benchmark. Since the new payment rule took effect on January 1, 1998, our study includes only one year in this period. This poses a number of limitations in the study. The conceptual concern is about using only the implementation date to study the effects of the new payment rule. Essentially, in doing that, we are assuming that the industry was either unaware of the legislative reform or it chose not to react to the impending new payment rule until it was enacted and implemented. If the industry reacted to the anticipated revision of the payment rule by raising AWP's before the implementation, this estimate would fail to capture that response. The analytical concern is the limitation that we have only one year to examine any changes in the trend. A longer time period would be required for a more accurate assessment of a time trend with a high statistical level of confidence.

With these caveats, the results of this second analysis are presented in Figure 5.

---

<sup>3</sup> We note that the industry-wide average AWP in each drug class has a high (95 percent - 99 percent) level of statistical significance, but the Medicare drug indices have a marginal statistical significance ranging from 80 percent - 85 percent.



Comparing the overall trend to the behavior in the last year, AWP inflation rates for both brand single source drugs and brand multi-source drugs were slightly lower than their earlier annual average rates, while the generic drug index shows an inflation of 9.14 percent.<sup>4</sup> Although this seems a significantly high rate of inflation, the industry-wide comparison group shows a nearly identical inflation rate. The industry-wide average inflation for the generic drugs was 9.21 percent in 1998.

The result of our analysis depends on the choice of the benchmark period. Assuming that the industry either had no knowledge of the impending legislative reform or that the industry would not respond to it until it was implemented, the conclusion would be that the AWP in 1998 is consistent with the long term pricing trends in the industry for the brand single source drugs and brand multi-source drugs. By contrast, the generic drug industry average AWP showed a substantial increase in 1998. However, this is not necessarily the generic industry's response to offset the effects of the BBA payment reform. This is because the AWP inflation rate of 9.14 percent for the Medicare-covered generic drugs parallels closely the growth rate of the industry-wide AWP, which presumably was not affected by the BBA reform.

More probable is the assumption that the industry began responding to the legislative initiative when first introduced rather than the implementation of the revised payment rule. In addition, we could conjecture that brand drugs may have begun reacting to the legislation before the generic industry. Under this assumption, 1997 and 1998 were grouped together to examine the effect of the BBA change. The results indicate that all three drug groups showed a higher AWP inflation rate in the post-BBA period. This high AWP growth rate is in apparent contrast to the slowdown of the CPI-Rx during the same period.

#### V. Conclusion

Our basic conclusion is that there is no statistically measurable difference in the rate of increase in AWP after the statutory change in Medicare program payment for drugs as compared to before the change. We can only speculate about the reason for this. It may be that drug manufacturers decided to wait to offset the 5 percent reduction until after the report is written since there was only about one year between the effective date of the reduction and the time we had to collect the data for the report. It may be that there are

---

<sup>4</sup> It is notable that price revision is less frequent among the generic drugs than among the brand drugs. However, while generic drug revisions are less frequent, they tend to be larger increase when they occur. Under this alternative benchmark, results are generally statistically insignificant.

so few drugs for which Medicare is the primary market (there are only 36 specific drugs of \$10 million or more in Medicare allowed charges, and only 12 specific drugs of \$50 million or more) that total drug sales are generally not affected significantly by Medicare's payment amount. Another possible explanation is that a 5 percent reduction may have been relatively minor compared to the average profit margin for drugs covered by Medicare. If this is so, either the drug manufacturer or the wholesaler may have absorbed the reduction and lowered the real market price to the physicians purchasing the drugs.

As shown by table 3, the rate of increase for the Medicare generic AWP drug group increased abruptly in 1998, but not as much as the industry-wide generic AWP group. Therefore, we do not believe this is due to the change in Medicare pricing policy. It may be that generic drug AWP's were historically low and are simply catching up with brand drug AWP's in the past year or two.

Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace.

#### Appendix

The AWP file contains the current and historical AWP's and effective dates of each AWP. These AWP's were converted to a quarterly time series of price data. If a particular drug product was available at the beginning of the observation period (i.e., the first quarter of 1992), then the AWP at the beginning of the observation period became the base for that drug. The base for drugs that entered the market at a later time was the AWP at the time of entry into the marketplace.

By dividing the price series by the first available price, we created a normalized price series with the first observation value being one, and all subsequent price changes expressed as a proportional ratio to the original value. Based on this normalized price series, we calculated quarterly price adjustment rates. A simple average of price changes was then computed for each class of drugs. The price indices were constructed by multiplying these average periodic adjustment rates to the base value of one. This method has the disadvantage of missing the initial effect of a new product at the time of entry into the market. However, it captures any subsequent price changes. This method effectively deals with the problem of incorporating new drug prices into an index.

Table 1. Medicare Part B Top 50 Drug-Related Procedures in 1997

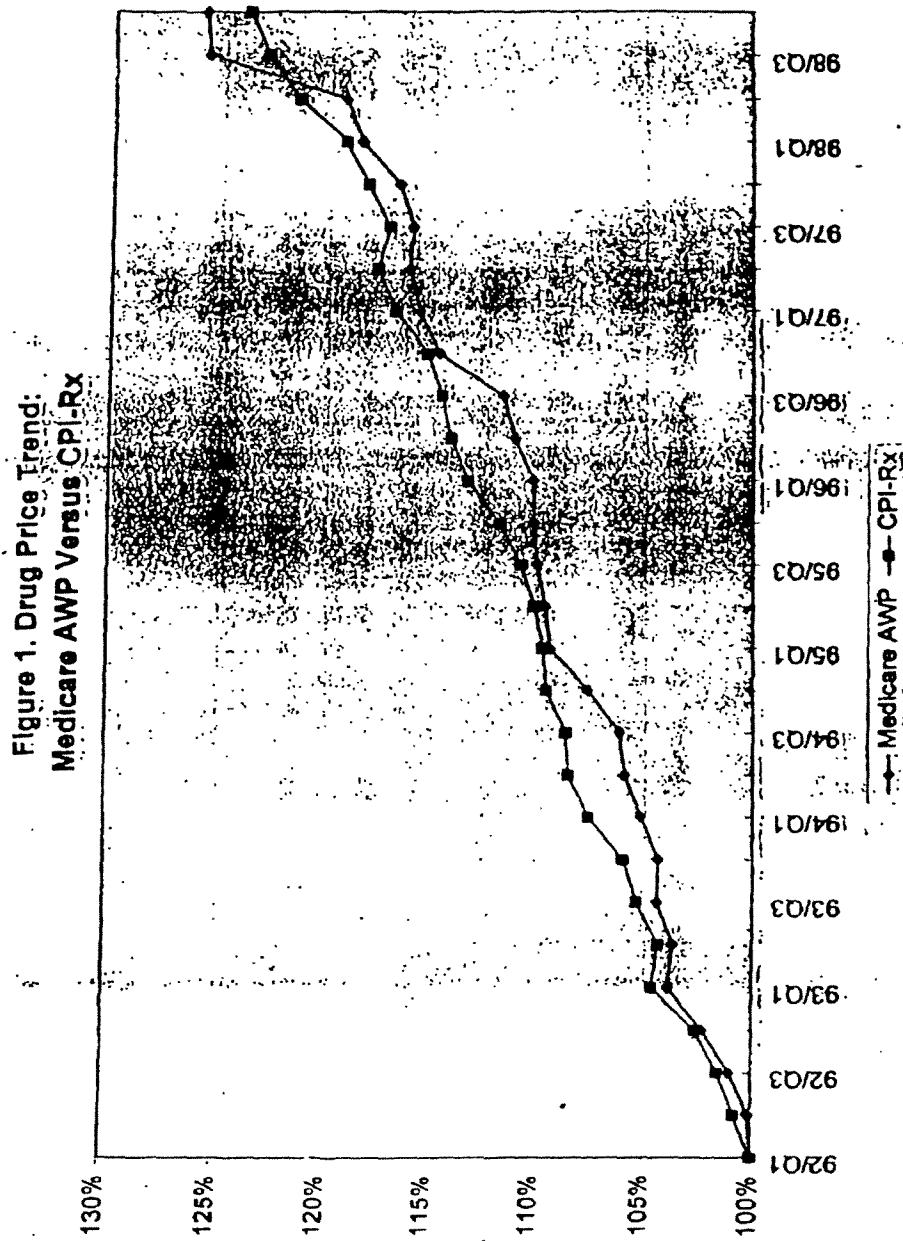
Rank	HCPC	Code Description	Service Frequency	Total Charge in \$	Charge%
1	J9217	Leuprolide acetate suspension	1,293,637	643,733,319	22.75
2	K0505	Albuterol inhalation solution	481,660,654	206,532,197	7.30
3	J9265	Paclitaxel injection	909,269	163,021,593	5.76
4	J9999*	Chemotherapy drug	639,415	141,985,451	5.02
5	J9202	Goserelin acetate implant	332,604	132,061,675	4.67
6	Q0136	Epoetin alpha	10,734,693	128,513,533	4.54
7	K0518	Ipratropium bromide inh solution	54,217,683	115,919,620	4.10
8	J9045	Carboplatin injection	991,120	85,471,778	3.02
9	J1625	Granisetron hydrochloride	415,365	68,458,154	2.42
10	J0640	Leucovorin calcium injection	2,797,743	58,961,589	2.08
11	J1440	Filgrastim 300 mcg injection	373,269	56,920,518	2.01
12	J2405	Ondansetron hcl injection	8,813,084	53,555,285	1.89
13	90724*	Influenza immunization	11,275,541	50,183,001	1.77
14	J1441	Filgrastim 480 mcg injection	197,577	48,908,852	1.71
15	J2430	Pamidronate disodium	232,980	45,204,074	1.60
16	J1562	Immune globulin 10% / 5 grams	951,464	44,421,038	1.57
17	J1561*	Immune globulin injection	1,058,250	42,339,876	1.50
18	90780*	"IV infusion therapy, 1 hour"	880,191	33,205,117	1.17
19	J1921*	Factor VIII	3,102,993	32,210,870	1.14
20	J7190	Factor VIII	4,630,258	30,811,997	1.09
21	J9000*	Doxorubicin hcl	638,860	28,006,311	0.99
22	J3490	Drugs unclassified injection	786,761	24,611,907	0.87
23	J9182	Etoposide 100 mg inj	182,771	23,135,330	0.82
24	90732	Pneumococcal immunization	1,811,047	22,752,453	0.80
25	J9293	Mitomycin hydrochl / 5 MG	122,958	21,856,470	0.77
26	J9390	Vinorelbine tartrate / 10 MG	353,916	20,488,196	0.72
27	K0418	Cyclosporine oral 100 MG	3,810,721	19,119,355	0.68
28	J9185	Fludarabine phosphate inj	103,374	19,040,183	0.67
29	K0412	Mycophenolate mofetil oral 250	9,963,364	18,878,408	0.67
30	K0503	Acetylcysteine inh sol u d	6,311,548	18,686,188	0.66
31	J9031	Bcg live intravesical vac	116,040	17,752,520	0.63
32	J0150	Adenosine 6 MG inj	740,917	15,258,996	0.54
33	J7699*	Inhalation solution for DME	25,329,126	14,593,808	0.52
34	J0696	Ceftriaxone sodium injection	1,138,348	13,324,429	0.47
35	J7050	Normal saline solution infus	1,463,942	13,167,307	0.47
36	J1245	Dipyridamole injection	523,190	12,900,629	0.46
37	J0585	Botulinum toxin a per 100 u	2,931,031	12,374,432	0.44
38	J9214	Interferon alfa-2b inj	1,119,421	12,309,847	0.43
39	J2820	Sargramostim injection	514,378	12,238,227	0.43
40	J9181	Etoposide 10 MG inj	886,144	11,995,065	0.42
41	J1785	Imiglucerase /unit inj	2,111,081	11,625,547	0.41
42	J9062	Cisplatin 50 MG injection	62,202	10,612,402	0.37
43	J9291	Mitomycin 40 MG inj	12,470	10,271,455	0.36
44	J7196	Hemophilia clot factors othr	892,001	9,941,853	0.35
45	90781*	"IV infusion, additional hour"	521,623	9,803,333	0.35
46	J9060	Cisplatin 10 MG injection	256,849	9,183,982	0.32
47	J7507	Tacrolimus oral per 1 MG	3,874,791	9,035,128	0.32
48	K0524	Metaproterenol inh sol u d	9,889,294	8,894,485	0.31
49	90799*	Therapeutic/diag injection	192,945	7,260,298	0.26
50	J9213	Interferon alfa-2a inj	202,687	6,461,028	0.23

HHC902-0811

Table 2. Classification of Drugs

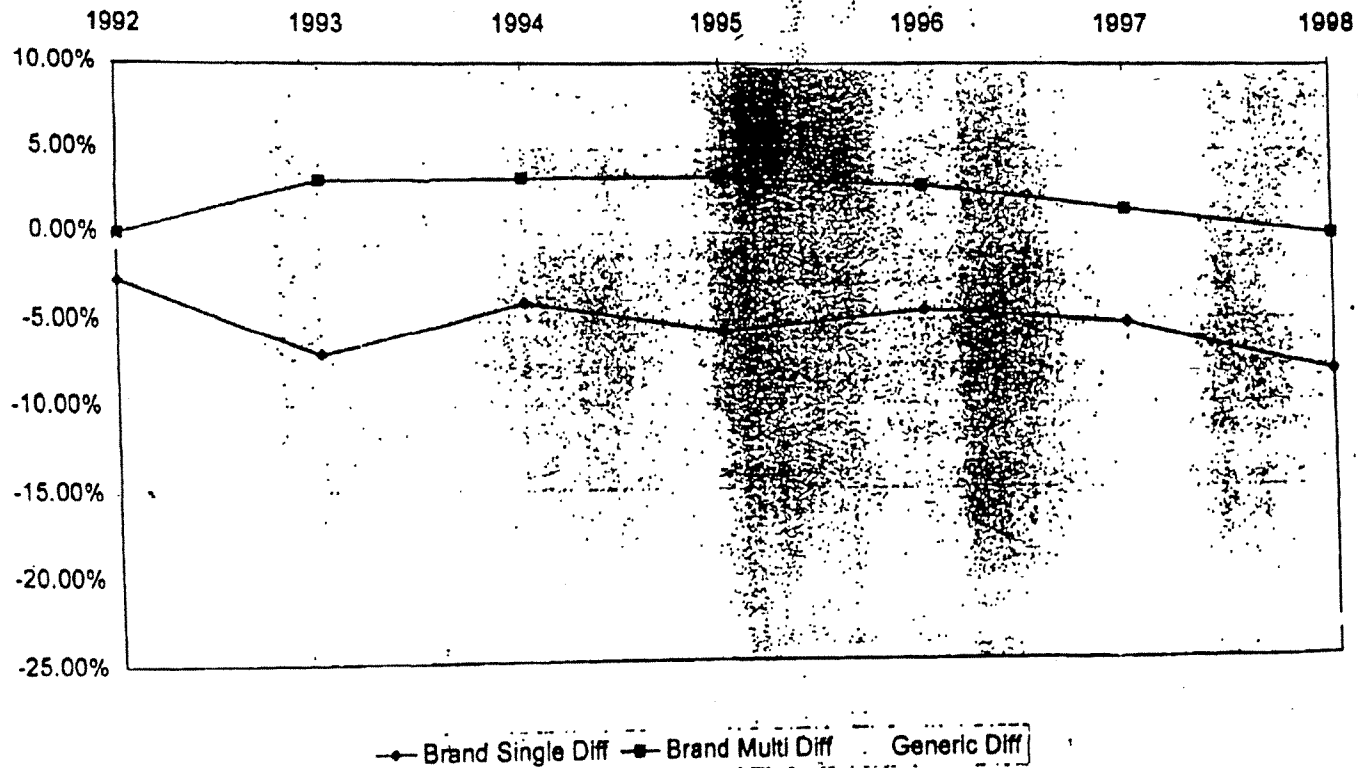
	Manufactured Under Patent	Manufactured Off-Patent
Exclusive Marketing	Brand Single-source Drugs	None
Nonexclusive Marketing	Brand Multi-source Drugs	Generic Drugs

HHC902-0812



HHC902-0813

Figure 2. MEDICARE AWP INDEX Minus MARKET AWP



HHC902-0814

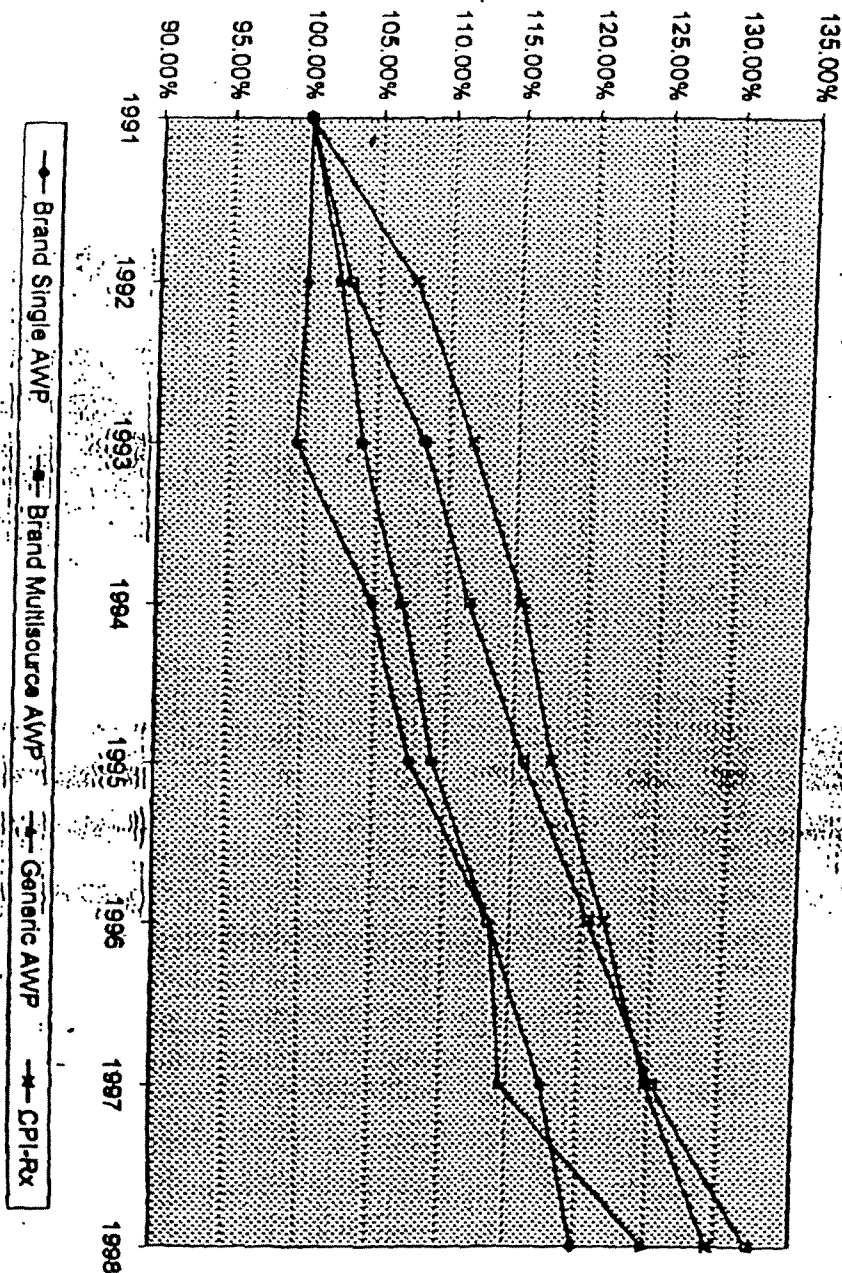


Table 3. Annual Inflation of AWP's and CPI-Rx

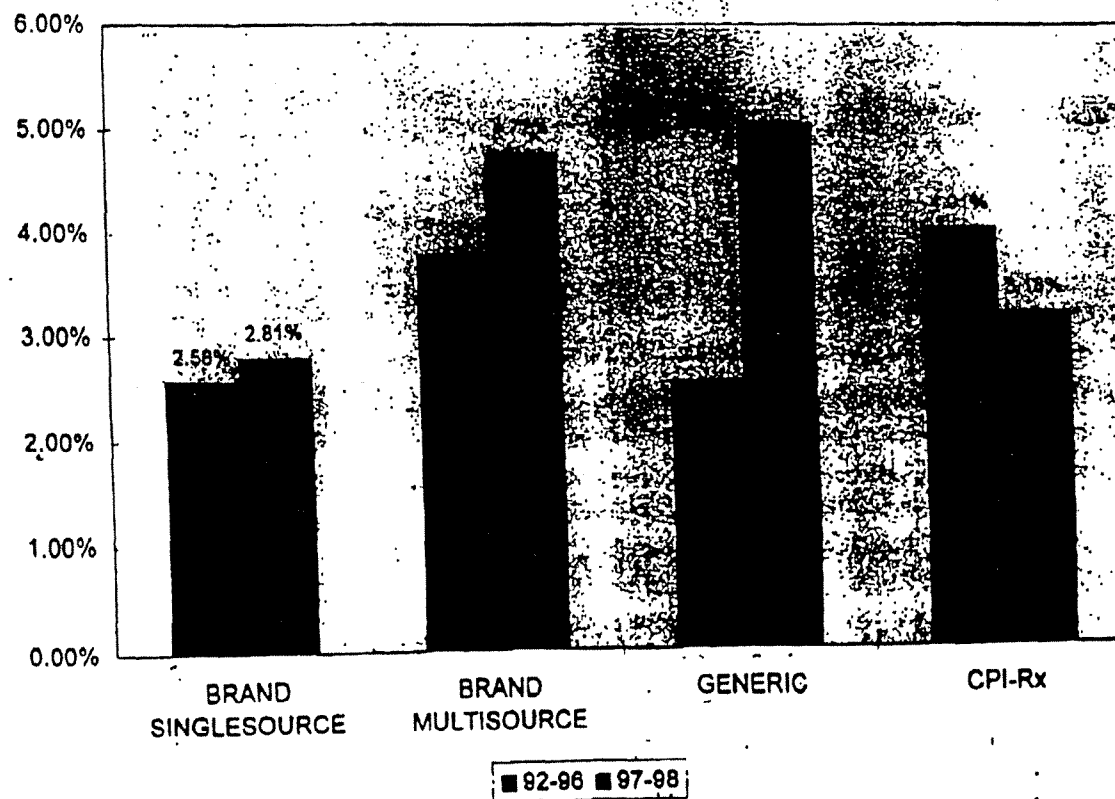
	1992	1993	1994	1995	1996	1997	1998	Average
MEDICARE BRAND SINGLE	0.00%	-0.63%	5.50%	2.57%	5.44%	3.54%	2.07%	2.64%
ALL BRAND SINGLE	2.72%	3.60%	2.29%	4.02%	4.09%	4.08%	4.45%	3.60%
MEDICARE BRAND MULTI	2.98%	5.08%	3.16%	3.64%	4.14%	3.97%	5.57%	4.08%
ALL BRAND MULTI	2.98%	2.00%	3.13%	3.70%	4.70%	5.29%	6.85%	4.08%
MEDICARE GENERIC	2.31%	1.57%	2.88%	2.01%	3.89%	0.94%	9.14%	3.26%
ALL GENERIC	2.90%	6.92%	4.47%	7.05%	5.09%	4.87%	9.21%	5.78%
CPI-Rx	7.51%	3.87%	3.41%	1.91%	3.36%	2.63%	3.73%	3.77%

HHC902-0815

JHC902-0816

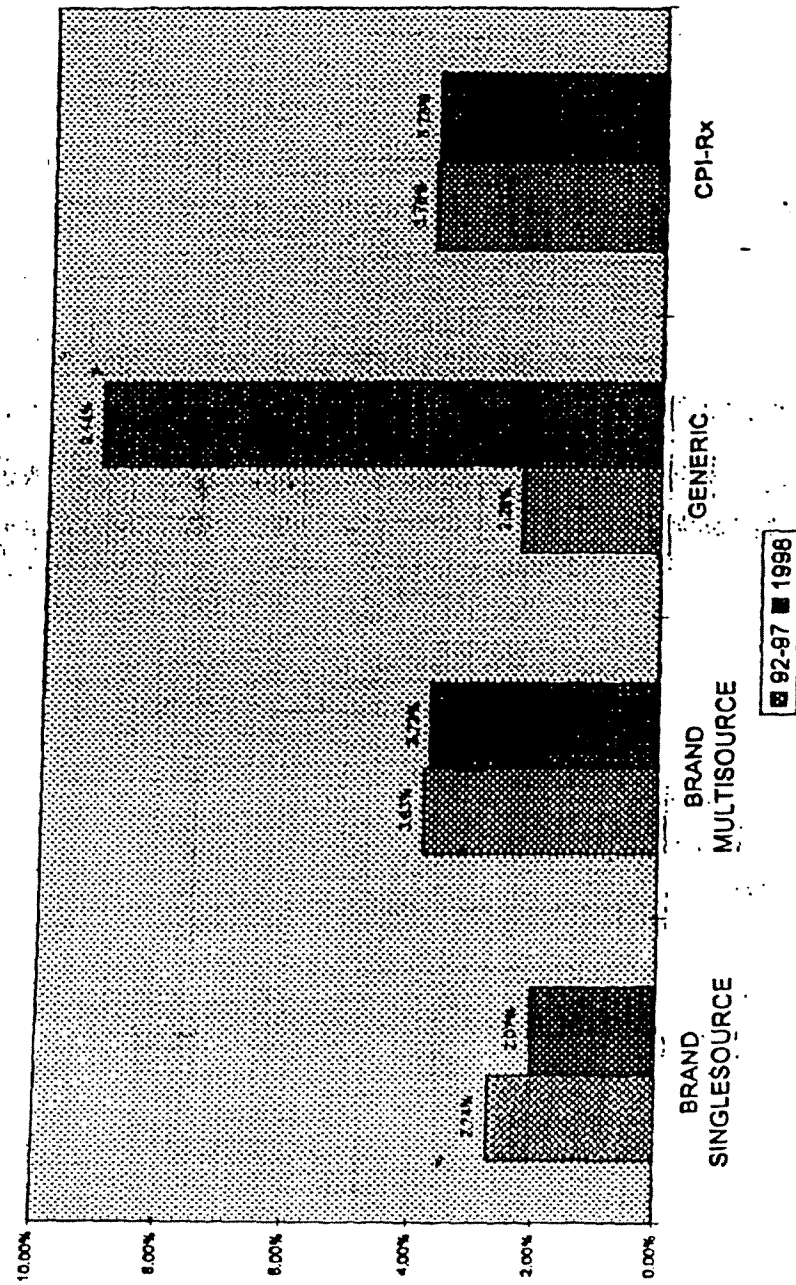


**Figure 4. Medicare AWP Average Inflation:  
1992-96 Versus 1997-98**



HH902-0817

Figure 5. Medicare AWP Average Inflation:  
1992-1997 Versus 1998



HHC902-0818